General

Guideline Title

Psoriasis: the assessment and management of psoriasis.

Bibliographic Source(s)

National Clinical Guideline Centre. Psoriasis: the assessment and management of psoriasis. London (UK): National Institute for Health and Clinical Excellence (NICE); 2012 Oct. 61 p. (Clinical guideline; no. 153).

Guideline Status

This is the current release of the guideline.

Recommendations

Major Recommendations

Note from the National Guideline Clearinghouse (NGC): This guideline was developed by the National Clinical Guideline Centre (NCGC) on behalf of the National Institute for Health and Clinical Excellence (NICE) (see the "Availability of Companion Documents" field for the full version of this guidance).

Principles of Care

Offer people with any type of psoriasis (and their families or carers), support and information tailored to suit their individual needs and circumstances, in a range of different formats so they can confidently understand:

- Their diagnosis and treatment options
- Relevant lifestyle risk factors
- When and how to treat their condition
- How to use prescribed treatments safely and effectively (for example, how to apply topical treatments, how to minimise the risk of side effects through monitoring for safety of medicines)
- When and how to seek further general or specialist review
- Strategies to deal with the impact on their physical, psychological and social wellbeing

When offering treatments to a person with any type of psoriasis:

- Ensure the treatment strategy is developed to meet the person's health goals so that the impact of their condition is minimised and use relevant assessment tools to ensure these goals are met
- Take into account the age and individual circumstances of the person, disease phenotype, severity and impact, co-existing psoriatic arthritis, comorbidities and previous treatment history

- Discuss the risks and benefits of treatment options with the person (and their families or carers where appropriate). Where possible use absolute risk and natural frequency (see Appendix B in the full guideline for details of the risk-benefit profiles of interventions recommended in this guideline)
- Discuss the importance of adherence to treatment for optimising outcomes

For more information about involving patients in decisions and supporting adherence see Medicines adherence (NICE clinical guideline 76).

Assess whether support and information need updating or revising at every review or interaction with the person, in particular:

- During transition from children's services to adult services
- When new interventions become available
- When the person's disease severity or circumstances (for example, in terms of comorbidities or lifestyle) change

Provide a single point of contact to help people with all types of psoriasis (and their families or carers where appropriate) access appropriate information and advice about their condition and the services available at each stage of the care pathway.

NICE has produced guidance on the components of good patient experience in adult National Health Service (NHS) services. All healthcare professionals should follow the recommendations in Patient experience in adult NHS services (NICE clinical guideline 138).

Assessment and Referral

Assessment Tools for Disease Severity and Impact and When to Refer for Specialist Care

For people with any type of psoriasis assess:

- Disease severity
- The impact of disease on physical, psychological and social wellbeing
- Whether they have psoriatic arthritis
- The presence of comorbidities

Assess the severity and impact of any type of psoriasis:

- At first presentation
- Before referral for specialist advice and at each referral point in the treatment pathway
- To evaluate the efficacy of interventions

When assessing the disease severity in any healthcare setting, record:

- The results of a static Physician's Global Assessment (classified as clear, nearly clear, mild, moderate, severe or very severe) (Feldman & Krueger, 2005)
- The patient's assessment of current disease severity, for example, using the static Patient's Global Assessment (classified as clear, nearly clear, mild, moderate, severe or very severe)
- The body surface area affected
- Any involvement of nails, high-impact and difficult-to-treat sites (for example, the face, scalp, palms, soles, flexures and genitals)
- Any systemic upset such as fever and malaise, which are common in unstable forms of psoriasis such as erythroderma or generalised pustular psoriasis

In specialist settings, use a validated tool to assess severity of psoriasis, for example the Psoriasis Area and Severity Index (PASI) (see Psoriasis Area and Severity Index; the PASI is also available from the British Association of Dermatologists Web site) in addition to the assessments indicated above.

Be aware that:

- PASI and body surface area are not validated for use in children and young people
- Erythema may be underestimated in people with darker skin types, such as skin types V and VI on the Fitzpatrick scale (Fitzpatrick scale: type I: always burns, never tans; type II: usually burns, tans with difficulty, type III: sometimes mild burn, gradually tans; type IV: rarely burns, tans with ease; type V: very rarely burns, tans very easily; type VI: never burns, tans very easily).

Use the Nail Psoriasis Severity Index (Rich & Scher, 2003) to assess nail disease in specialist settings:

- If there is a major functional or cosmetic impact or
- Before and after treatment is initiated specifically for nail disease

Assess the impact of any type of psoriasis on physical, psychological and social wellbeing by asking:

- What aspects of their daily living are affected by the person's psoriasis
- How the person is coping with their skin condition and any treatments they are using
- If they need further advice or support
- If their psoriasis has an impact on their mood
- If their psoriasis causes them distress (be aware the patient may have levels of distress and not be clinically depressed)
- If their condition has any impact on their family or carers

Ask children and young people age-appropriate questions.

In specialist settings, and if practical in non-specialist settings, use a validated tool to assess the impact of any type of psoriasis on physical, psychological and social wellbeing, for example the:

- Dermatology Life Quality Index (DLQI)* for adults or
- Children's Dermatology Life Quality Index (CDLQI) for children and young people.

When using an assessment tool for a person with any type of psoriasis:

- Take account of their age, any disabilities (such as physical, visual or cognitive impairment), and any language or other communication difficulties, and provide help and support if needed*
- Ensure that the chosen assessment tool continues to be a sufficiently accurate measure

*See Dermatology Life Quality Index. The DLQI is also available from the British Association of Dermatologists Web site.

Following assessment in a non-specialist setting, refer people for dermatology specialist advice if:

- There is diagnostic uncertainty or
- Any type of psoriasis is severe or extensive, for example more than 10% of the body surface area is affected or
- Any type of psoriasis cannot be controlled with topical therapy or
- Acute guttate psoriasis requires phototherapy (see recommendation in Phototherapy section below) or
- Nail disease has a major functional or cosmetic impact or
- Any type of psoriasis is having a major impact on a person's physical, psychological or social wellbeing

People with generalised pustular psoriasis or erythroderma should be referred immediately for same-day specialist assessment and treatment.

Refer children and young people with any type of psoriasis to a specialist at presentation.

Assessment and Referral for Psoriatic Arthritis

Offer annual assessment for psoriatic arthritis to people with any type of psoriasis. Assessment is especially important within the first 10 years of onset of psoriasis.

Use a validated tool to assess adults for psoriatic arthritis in primary care and specialist settings, for example the Psoriasis Epidemiological Screening Tool (PEST) (Ibrahim et al., 2009). The PEST questionnaire is reproduced in Appendix T of the full guideline). Be aware that the PEST does not detect axial arthritis or inflammatory back pain.

As soon as psoriatic arthritis is suspected, refer the person to a rheumatologist for assessment and advice about planning their care.

Identification of Comorbidities

Offer adults with severe psoriasis (severe psoriasis was defined as either requiring treatment with phototherapy or systemic agents or requiring hospital admission in the studies underpinning this recommendation) of any type a cardiovascular risk assessment at presentation using a validated risk estimation tool. Offer further assessment of cardiovascular risk every 5 years, or more frequently if indicated following assessment. For further information see Lipid modification (NICE clinical guideline 67).

Discuss risk factors for cardiovascular comorbidities with people who have any type of psoriasis (and their families or carers where appropriate). Where appropriate offer preventative advice, healthy lifestyle information and support for behavioural change tailored to meet the needs of the individual in line with the following NICE guidance:

- Lipid modification (NICE clinical guideline 67)
- Obesity (NICE clinical guideline 43)
- Preventing type 2 diabetes: population and community interventions (NICE public health guidance 35)
- Prevention of cardiovascular disease (NICE public health guidance 25)
- Alcohol-use disorders: preventing harmful drinking (NICE public health guidance 24)
- Smoking cessation services (NICE public health guidance 10)
- Four commonly used methods to increase physical activity (NICE public health guidance 2)
- Promoting physical activity in the workplace (NICE public health guidance 13)
- Promoting physical activity for children and young people (NICE public health guidance 17).

For people with multiple comorbidities and/or multimorbidities and any type of psoriasis needing second- or third-line therapy, ensure multidisciplinary working and communication between specialties and, if needed, interdisciplinary team working (for example when both skin and joints are significantly affected).

Be aware that psoriasis of any type, especially if severe (severe psoriasis was identified by hospitalisations [including outpatient visits] for psoriasis [International Classification of Diseases {ICD}-10 L40] or psoriatic arthritis), is a risk factor for venous thromboembolism in adults, and:

- Explain this risk to adults with any type of psoriasis
- Offer advice on how to minimise the risk (for example, during hospital admission, surgery, or periods of immobility)
- Manage the risk in line with Venous thromboembolismin adults admitted to hospital: reducing the risk (see the NGC summary of NICE clinical guideline 92).

Assess whether people with any type of psoriasis are depressed when assessing disease severity and impact, and when escalating therapy. If appropriate offer information, advice and support in line with Depression in adults with a chronic physical health problem (NICE clinical guideline 91) and Depression in children and young people (NICE clinical guideline 28).

Topical Therapy

The treatment pathway in this guideline begins with active topical therapies. The Guideline Development Group (GDG) acknowledged that the use of emollients in psoriasis was already widespread and hence the evidence review was limited to active topical therapies for psoriasis. Please refer to the British National Formulary (BNF) and BNF for children (cBNF) for guidance on use of emollients.

General Recommendations

Offer people with psoriasis topical therapy as first-line treatment.

Offer second- or third-line treatment options (phototherapy or systemic therapy) at the same time when topical therapy alone is unlikely to adequately control psoriasis, such as:

- Extensive disease (for example more than 10% of body surface area affected) or
- At least 'moderate' on the static Physician's Global Assessment or
- Where topical therapy is ineffective, such as nail disease

Offer practical support and advice about the use and application of topical treatments. Advice should be provided by healthcare professionals who are trained and competent in the use of topical therapies. Support people to adhere to treatment in line with Medicines adherence (NICE clinical guideline 76).

When offering topical agents:

- Take into account patient preference, cosmetic acceptability, practical aspects of application and the site(s) and extent of psoriasis to be treated
- Discuss the variety of formulations available and, depending on the person's preference, use:
    - Cream, lotion or gel for widespread psoriasis

    - Lotion, solution or gel for the scalp or hair-bearing areas
    - Ointment to treat areas with thick adherent scale
- Be aware that topical treatment alone may not provide satisfactory disease control, especially in people with psoriasis that is extensive (for example more than 10% of body surface area affected) or at least 'moderate' on the static Physician's Global Assessment.

If a person of any age with psoriasis requiring topical therapy has a physical disability, or cognitive or visual impairment offer advice and practical support that take into account the person's individual needs.

Arrange a review appointment 4 weeks after starting a new topical treatment in adults, and 2 weeks after starting a new topical treatment in children, to:

- Evaluate tolerability, toxicity, and initial response to treatment (including measures of severity and impact described in recommendations in the "Assessment Tools for Disease Severity and Impact and When to Refer for Specialist Care" section above)
- Reinforce the importance of adherence when appropriate
- Reinforce the importance of a 4 week break between courses of potent/very potent corticosteroids (see recommendation in the "How to Use Corticosteroids Safely" section below).

If there is little or no improvement at this review, discuss the next treatment option with the person.

Discuss with people whose psoriasis is responding to topical treatment (and their families or carers where appropriate):

- The importance of continuing treatment until a satisfactory outcome is achieved (for example clear or nearly clear) or up to the recommended maximum treatment period for corticosteroids (see recommendations in the following sections)
- That relapse occurs in most people after treatment is stopped
- That after the initial treatment period topical treatments can be used when needed to maintain satisfactory disease control

Offer people with psoriasis a supply of their topical treatment to keep at home for the self-management of their condition.

In people whose psoriasis has not responded satisfactorily to a topical treatment strategy, before changing to an alternative treatment:

- Discuss with the person whether they have any difficulties with application, cosmetic acceptability or tolerability and where relevant offer an alternative formulation
- Consider other possible reasons for non-adherence in line with Medicines adherence (NICE clinical guideline 76).

How to Use Corticosteroids Safely (see recommendations in later sections for details on safe use of steroids at facial, flexural and genital sites)

Be aware that continuous use of potent or very potent corticosteroids may cause:

- Irreversible skin atrophy and striae
- Psoriasis to become unstable
- Systemic side effects when applied continuously to extensive psoriasis (for example more than 10% of body surface area affected)

Explain the risks of these side effects to people undergoing treatment (and their families or carers where appropriate) and discuss how to avoid them.

Aim for a break of 4 weeks between courses of treatment with potent or very potent corticosteroids. Consider topical treatments that are not steroid-based (such as vitamin D or vitamin D analogues or coal tar) as needed to maintain psoriasis disease control during this period.

When offering a corticosteroid for topical treatment select the potency and formulation based on the person's need.

Do not use very potent corticosteroids continuously at any site for longer than 4 weeks.

Do not use potent corticosteroids continuously at any site for longer than 8 weeks.

Do not use very potent corticosteroids in children and young people.

Offer a review at least annually to adults with psoriasis who are using intermittent or short-term courses of a potent or very potent corticosteroid (either as monotherapy or in combined preparations) to assess for the presence of steroid atrophy and other adverse effects. See recommendations above for details on safe duration of steroid use.

Offer a review at least annually to children and young people with psoriasis who are using corticosteroids of any potency (either as monotherapy or in combined preparations) to assess for the presence of steroid atrophy and other adverse effects.

Topical Treatment of Psoriasis Affecting the Trunk and Limbs

Offer a potent corticosteroid applied once daily plus vitamin D or a vitamin D analogue applied once daily (applied separately, one in the morning and the other in the evening) for up to 4 weeks as initial treatment for adults with trunk or limb psoriasis.

If once-daily application of a potent corticosteroid plus once-daily application of vitamin D or a vitamin D analogue does not result in clearance, near clearance or satisfactory control of trunk or limb psoriasis in adults after a maximum of 8 weeks, offer vitamin D or a vitamin D analogue alone applied twice daily.

If twice-daily application of vitamin D or a vitamin D analogue does not result in clearance, near clearance or satisfactory control of trunk or limb psoriasis in adults after 8 to 12 weeks, offer either:

- A potent corticosteroid applied twice daily for up to 4 weeks or
- A coal tar preparation applied once or twice daily

If a twice-daily potent corticosteroid or coal tar preparation cannot be used or a once-daily preparation would improve adherence in adults offer a combined product containing calcipotriol monohydrate and betamethasone dipropionate applied once daily for up to 4 weeks.

Offer treatment with very potent corticosteroids in adults with trunk or limb psoriasis only:

- In specialist settings under careful supervision
- When other topical treatment strategies have failed
- For a maximum period of 4 weeks

Consider short-contact dithranol for treatment-resistant psoriasis of the trunk or limbs and either:

- Give educational support for self-use or
- Ensure treatment is given in a specialist setting

For children and young people with trunk or limb psoriasis consider either:

- Calcipotriol applied once daily (only for those over 6 years of age) or
- A potent corticosteroid applied once daily (only for those over 1 year of age)

Refer to the BNF for children for information on appropriate dosing and duration of treatment.

Topical Treatment of Psoriasis Affecting the Scalp

Note: Only use potent corticosteroids according to UK marketing authorisation, which was limited to those over 1 year of age at the time of publication (October 2012). In children and young people the specified duration of therapy may not be appropriate. Please refer to the BNF for children for information on appropriate dosing and duration of treatment.

Offer a potent corticosteroid applied once daily for up to 4 weeks as initial treatment for people with scalp psoriasis.

Show people with scalp psoriasis (and their families or carers where appropriate) how to safely apply corticosteroid topical treatment.

If treatment with a potent corticosteroid does not result in clearance, near clearance or satisfactory control of scalp psoriasis after 4 weeks consider:

- A different formulation of the potent corticosteroid (for example, a shampoo or mousse) and/or
- Topical agents to remove adherent scale (for example, agents containing salicylic acid, emollients and oils) before application of the potent corticosteroid.

If the response to treatment with a potent corticosteroid for scalp psoriasis remains unsatisfactory after a further 4 weeks of treatment offer:

- A combined product containing calcipotriol monohydrate and betamethasone dipropionate applied once daily for up to 4 weeks or
- Vitamin D or a vitamin D analogue applied once daily (only in those who cannot use steroids and with mild to moderate scalp psoriasis)

Note: At the time of publication (October 2012), the combined product containing calcipotriol monohydrate and betamethasone dipropionate did not have UK marketing authorisation for this indication in children and young people. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. The patient (or their parent or carer) should provide informed consent, which should be documented. See the General Medical Council's Good practice in prescribing medicines – guidance for doctors for further information. In children, when offering an agent in the vitamin D or vitamin D analogue class choose calcipotriol, because at the time of publication

(October 2012) calcitriol and tacalcitol did not have UK marketing authorisation for this group.

If continuous treatment with either a combined product containing calcipotriol monohydrate and betamethasone dipropionate applied once daily or vitamin D or a vitamin D analogue applied once daily for up to 8 weeks does not result in clearance, near clearance or satisfactory control of scalp psoriasis offer:

- A very potent corticosteroid applied up to twice daily for 2 weeks for adults only or
- Coal tar applied once or twice daily or
- Referral to a specialist for additional support with topical applications and/or advice on other treatment options

Consider topical vitamin D or a vitamin D analogue alone for the treatment of scalp psoriasis only in people who:

- Are intolerant of or cannot use topical corticosteroids at this site or
- Have mild to moderate scalp psoriasis

Note: In children, when offering an agent in the vitamin D or vitamin D analogue class choose calcipotriol, because at the time of publication (October 2012) calcitriol and tacalcitol did not have UK marketing authorisation for this group. Please refer to the BNF for children for information on appropriate dosing and duration of treatment.

Do not offer coal tar-based shampoos alone for the treatment of severe scalp psoriasis.

Topical Treatment of Psoriasis Affecting the Face, Flexures and Genitals

Offer a short-term mild or moderate potency corticosteroid applied once or twice daily (for a maximum of 2 weeks) to people with psoriasis of the face, flexures or genitals.

Note: At the time of publication (October 2012), moderate potency corticosteroids did not have UK marketing authorisation for this indication. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. The patient (or their parent or carer) should provide informed consent, which should be documented. See the General Medical Council's Good practice in prescribing medicines – guidance for doctors for further information. In children and young people the specified duration of therapy may not be appropriate. Please refer to the BNF for children for information on appropriate dosing and duration of treatment.

Be aware that the face, flexures and genitals are particularly vulnerable to steroid atrophy and that corticosteroids should only be used for short-term treatment of psoriasis (1 to 2 weeks per month). Explain the risks to people undergoing this treatment (and their families or carers where appropriate) and how to minimise them.

For adults with psoriasis of the face, flexures or genitals if the response to short-term moderate potency corticosteroids is unsatisfactory, or they require continuous treatment to maintain control and there is serious risk of local corticosteroid-induced side effects, offer a calcineurin inhibitor applied twice daily for up to 4 weeks. Calcineurin inhibitors should be initiated by healthcare professionals with expertise in treating psoriasis.

Note: At the time of publication (October 2012), calcineurin inhibitors did not have UK marketing authorisation for this indication. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. The patient (or their parent or carer) should provide informed consent, which should be documented. See the General Medical Council's Good practice in prescribing medicines – guidance for doctors for further information.

Do not use potent or very potent corticosteroids on the face, flexures or genitals.

When prescribing topical agents at facial, flexural and genital sites take into account that they may cause irritation and inform people undergoing treatment (and their families and carers where appropriate) of these risks and how to minimise them.

Phototherapy (Broad- or Narrow-band Ultraviolet B [UVB] Light and Psoralen plus UVA Light [PUVA]

Offer narrowband ultraviolet B (UVB) phototherapy to people with plaque or guttate-pattern psoriasis that cannot be controlled with topical treatments alone. Treatment with narrowband UVB phototherapy can be given 3 or 2 times a week depending on patient preference. Tell people receiving narrowband UVB that a response may be achieved more quickly with treatment 3 times a week.

Offer alternative second- or third-line treatment when:

- Narrowband UVB phototherapy results in an unsatisfactory response or is poorly tolerated or
- There is a rapid relapse following completion of treatment (rapid relapse is defined as greater than 50% of baseline disease severity within 3 months) or
- Accessing treatment is difficult for logistical reasons (for example, travel, distance, time off work or immobility) or
- The person is at especially high risk of skin cancer

Consider psoralen (oral or topical) with local ultraviolet A (PUVA) irradiation to treat palmoplantar pustulosis.

Note: At the time of publication (October 2012), psoralen did not have UK marketing authorisation for this or any indication. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. The patient (or their parent or carer) should provide informed consent, which should be documented. See the General Medical

Council's Good practice in prescribing medicines –guidance for doctors for further information.

When considering PUVA for psoriasis (plaque type or localised palmoplantar pustulosis) discuss with the person:

- Other treatment options
- That any exposure is associated with an increased risk of skin cancer (squamous cell carcinoma)
- That subsequent use of ciclosporin may increase the risk of skin cancer, particularly if they have already received more than 150 PUVA treatments
- That risk of skin cancer is related to the number of PUVA treatments

Do not routinely offer co-therapy with acitretin when administering PUVA.

Consider topical adjunctive therapy in people receiving phototherapy with broadband or narrowband UVB who:

- Have plaques at sites that are resistant or show an inadequate response (for example, the lower leg) to phototherapy alone, or at difficult-to-treat or high-need, covered sites (for example, flexures and the scalp), and/or
- Do not wish to take systemic drugs or in whom systemic drugs are contraindicated

Do not routinely use phototherapy (narrowband UVB, broadband UVB or PUVA) as maintenance therapy.

Ensure that all phototherapy equipment is safety-checked and maintained in line with local and national policy (see British Association of Dermatologists: working party report on minimum standards for phototherapy services).

Healthcare professionals who are giving phototherapy should be trained and competent in its use and should ensure an appropriate clinical governance framework is in place to promote adherence to the indications for and contraindications to treatment, dosimetry and national policy on safety standards for phototherapy (see British Association of Dermatologists: working party report on minimum standards for phototherapy services).

Risk of Skin Cancer and How to Minimise Risk

Do not use PUVA in people with psoriasis of any type and a genetic predisposition to skin cancer for example, xeroderma pigmentosum or familial melanoma.

Do not use PUVA when other appropriate treatments are available in:

- People with a personal history of skin cancer or
- People who have already received 150 PUVA treatments or
- Children

Use PUVA with caution or consider other treatment options in:

- People at risk of skin cancer (melanoma and non-melanoma type) (see 'Improving outcomes for people with skin tumours including melanoma' [NICE cancer service guidance])
- People with lighter skin types, such as skin types I or II on the Fitzpatrick scale (Fitzpatrick scale: type I: always burns, never tans; type II: usually burns, tans with difficulty, type III: sometimes mild burn, gradually tans; type IV: rarely burns, tans with ease; type V: very rarely burns, tans very easily; type VI: never burns, tans very easily)
- People who are likely to require ciclosporin or long-term methotrexate
- Young people

Offer lifetime skin cancer surveillance to people treated with PUVA who have:

- Had more than 150 PUVA treatments or
- Developed skin cancer

Ensure that a permanent record of the person's cumulative number of UV treatments is kept (for example, in a national record).

Systemic Therapy

General Recommendations

Responsibility for use of systemic therapy should be in specialist settings only. Certain aspects of supervision and monitoring may be delegated to

other healthcare professionals and completed in non-specialist settings, in which case, such arrangements should be formalised.

When offering systemic therapy, tailor the choice of agent and dosing schedule to the needs of the individual and include consideration of:

- The person's age
- Disease phenotype, pattern of activity and previous treatment history
- Disease severity and impact
- The presence of psoriatic arthritis (in consultation with a rheumatologist)
- Conception plans
- Comorbidities
- The person's views

Be aware of benefits of, contraindications to, and adverse effects associated with systemic treatments. Explain the risks and benefits to people undergoing this treatment (and their families or carers where appropriate), using absolute risks and natural frequencies when possible (see Appendix B in the full guideline for details of the risk-benefit profiles of interventions recommended in this guideline). Support and advice should be provided by healthcare professionals who are trained and competent in the use of systemic therapies.

When reviewing response to systemic therapy, take into account:

- Disease severity compared with baseline (for example, PASI baseline to endpoint score)
- Control of psoriatic arthritis disease activity (in consultation with a rheumatologist if necessary)
- The impact of the disease on the person's physical, psychological and social wellbeing
- The benefits versus the risks of continued treatment
- The views of the person undergoing treatment (and their family or carers where appropriate)

Monitor people using systemic treatment for all types of psoriasis in accordance with national and local drug guidelines and policy. Take appropriate action in the event of laboratory abnormalities or adverse events.

Offer adjunctive topical therapy to people with psoriasis using systemic therapy to optimise treatment outcomes.

Offer people with psoriasis who are starting treatment with a systemic non-biological or biological drug the opportunity to participate in long-term safety registries (for example the British Association of Dermatologists Biologic Interventions Register).

Systemic Non-biological Therapy

Offer systemic non-biological therapy to people with any type of psoriasis if:

- It cannot be controlled with topical therapy and
- It has a significant impact on physical, psychological or social wellbeing and
- One or more of the following apply:
    - Psoriasis is extensive (for example, more than 10% of body surface area affected or a PASI score of more than 10) or
    - Psoriasis is localised and associated with significant functional impairment and/or high levels of distress (for example severe nail disease or involvement at high-impact sites) or
    - Phototherapy has been ineffective, cannot be used or has resulted in rapid relapse (rapid relapse is defined as greater than 50% of baseline disease severity within 3 months).

Choice of Drugs

Offer methotrexate as the first choice of systemic agent for people with psoriasis who fulfil the criteria for systemic therapy (see previous recommendations).

Note: At the time of publication (October 2012), methotrexate did not have UK marketing authorisation for this indication in children and young people. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. The patient (or their parent or carer) should provide informed consent, which should be documented. See the General Medical Council's Good practice in prescribing medicines – guidance for doctors for further information.

In people with both active psoriatic arthritis and any type of psoriasis that fulfils the criteria for systemic therapy consider the choice of systemic agent in consultation with a rheumatologist.

Offer ciclosporin as the first choice of systemic agent for people who fulfil the criteria for systemic therapy and who:

- Need rapid or short-term disease control (for example a psoriasis flare) or

- Have palmoplantar pustulosis or
- Are considering conception (both men and women) and systemic therapy cannot be avoided

Note: At the time of publication (October 2012), ciclosporin did not have UK marketing authorisation for this indication in children and young people under 16 years of age. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. The patient (or their parent or carer) should provide informed consent, which should be documented. See the General Medical Council's Good practice in prescribing medicines – guidance for doctors for further information.

Consider changing from methotrexate to ciclosporin (or vice-versa) when response to the first-choice systemic treatment is inadequate.

Consider acitretin for adults, and in exceptional cases only for children and young people, in the following circumstances:

- If methotrexate and ciclosporin are not appropriate or have failed or
- For people with pustular forms of psoriasis

Drug Regimens

Use incremental dosing of methotrexate (for example, starting with an initial dose of 5 to 10 mg once a week) and gradually increase up to an effective dose and a maximum of 25 mg a week. Assess the treatment response after 3 months at the target dose of methotrexate and stop treatment if the response is inadequate (for example, a decrease of less than 75% in PASI score or a decrease of less than 50% in PASI score and 5 points in DLQI score).

Use the lowest possible therapeutic dose of methotrexate to maintain remission.

Use 2.5 to 3 mg/kg a day of ciclosporin. Escalate to 5 mg/kg a day after 4 weeks only when there is no response to the lower dose or when rapid disease control is necessary (for example in severe unstable disease). Assess the treatment response after 3 months at the optimum dose of ciclosporin and stop treatment if the response is inadequate (for example, less than a 75% decrease in PASI score or less than a 50% decrease in PASI score and less than 5 points in DLQI score).

Note: At the time of publication (October 2012), ciclosporin did not have UK marketing authorisation for this indication in children and young people under 16 years of age. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. The patient (or their parent or carer) should provide informed consent, which should be documented. See the General Medical Council's Good practice in prescribing medicines – guidance for doctors for further information.

Use the lowest possible therapeutic dose of ciclosporin to maintain remission for up to 1 year. Consider other treatment options when disease relapses rapidly on stopping ciclosporin therapy (rapid relapse is defined as greater than 50% of baseline disease severity within 3 months of stopping treatment). Do not use ciclosporin continuously for more than 1 year unless disease is severe or unstable and other treatment options, including systemic biological therapy, cannot be used.

Use incremental dosing of acitretin to minimise mucocutaneous side effects and achieve a target dose of 25 mg daily in adults. Consider dose escalation to a maximum of 50 mg daily when no other treatment options are available. Assess the treatment response after 4 months at the optimum dose of acitretin and stop treatment if the response is inadequate, for example:

- In plaque-type psoriasis, less than a 75% decrease in PASI score or less than a 50% decrease in PASI score and less than 5 points in DLQI score
- In pustular forms of psoriasis, not achieving clear or nearly clear on the static Physician's Global Assessment.

Methotrexate and Risk of Hepatotoxicity

When considering the risks and benefits of treating any type of psoriasis with methotrexate, be aware that methotrexate can cause a clinically significant rise in transaminases and that long-term therapy may be associated with liver fibrosis (see recommendations below).

Methotrexate and Monitoring for Hepatotoxicity

Before and during methotrexate treatment, offer the person with any type of psoriasis an evaluation for potential risk of hepatotoxicity. Use standard liver function tests and serial serum procollagen III levels to monitor for abnormalities during treatment with methotrexate, taking into account pre-existing risk factors (for example obesity, diabetes and alcohol use), baseline results and trends over time.

When using serum procollagen III levels to exclude liver fibrosis or cirrhosis, be aware that the:

- Test cannot be used in children and young people
- Results may be unreliable in people with psoriatic arthritis
- Estimated positive predictive value is 23% to 95% and the estimated negative predictive value is 89% to 100%.

Provide advice on modifiable risk factors for liver disease prior to and during therapy, including alcohol intake and weight reduction if appropriate

in line with Alcohol-use disorders: preventing harmful drinking (NICE public health guidance 24), and Obesity (NICE clinical guideline 43). For further advice on how to support attitude and behavioural change see Behaviour change (NICE public health guidance 6).

Seek timely specialist advice and consider referral to a clinician with expertise in liver disease if the results of liver tests are abnormal.

Systemic Biological Therapy

The GDG did not review evidence for any aspect of the use of a first biological agent because guidance on this is already available in the existing NICE technology appraisals (Etanercept and efalizumab for the treatment of adults with psoriasis [NICE technology appraisal guidance 103], Infliximab for the treatment of adults with psoriasis [see the NICE technology appraisal guidance 134], Adalimumab for the treatment of adults with psoriasis [NICE technology appraisal guidance 146] and Ustekinumab for the treatment of adults with moderate to severe psoriasis [see the NICE technology appraisal guidance 180]).

Biological agents for psoriasis should be initiated and supervised only by specialist physicians experienced in the diagnosis and treatment of psoriasis.

If a person has both psoriasis and psoriatic arthritis, take into account both conditions before initiating or making changes to biological therapy and manage their treatment in consultation with a rheumatologist (see also Etanercept, infliximab and adalimumab for the treatment of psoriatic arthritis [NICE technology appraisal guidance 199] and Golimumab for the treatment of psoriatic arthritis [NICE technology appraisal guidance 220]).

When using the DLQI, healthcare professionals should take into account any physical, sensory or learning disabilities, or communication difficulties that could affect the responses to the DLQI and make any adjustments they consider appropriate.

The following recommendations are replicated from the relevant NICE Technology Assessments (TAs) and are listed here in alphabetical order by drug.

Adalimumab

The recommendations in this section are from Adalimumab for the treatment of adults with psoriasis (NICE technology appraisal guidance 146).

Adalimumab is recommended as a treatment option for adults with plaque psoriasis for whom anti-tumour necrosis factor (TNF) treatment is being considered and when the following criteria are both met:

- The disease is severe as defined by a total PASI of 10 or more and a DLQI of more than 10.
- The psoriasis has not responded to standard systemic therapies including ciclosporin, methotrexate and PUVA; or the person is intolerant of, or has a contraindication to, these treatments.

Adalimumab should be discontinued in people whose psoriasis has not responded adequately at 16 weeks. An adequate response is defined as either:

- A 75% reduction in the PASI score (PASI 75) from when treatment started or
- A 50% reduction in the PASI score (PASI 50) and a 5-point reduction in DLQI from start of treatment

Etanercept

The recommendations in this section are from Etanercept and efalizumab for the treatment of adults with psoriasis (NICE technology appraisal guidance 103).

Etanercept, within its licensed indications, administered at a dose not exceeding 25 mg twice weekly is recommended for the treatment of adults with plaque psoriasis only when the following criteria are met:

- The disease is severe as defined by a total PASI of 10 or more and a DLQI of more than 10.
- The psoriasis has failed to respond to standard systemic therapies including ciclosporin, methotrexate and PUVA; or the person is intolerant to, or has a contraindication to, these treatments.

Etanercept treatment should be discontinued in patients whose psoriasis has not responded adequately at 12 weeks. Further treatment cycles are

not recommended in these patients. An adequate response is defined as either:

- A 75% reduction in the PASI score from when treatment started (PASI 75) or
- A 50% reduction in the PASI score (PASI 50) and a 5-point reduction in DLQI from when treatment started

Infliximab

The recommendations in this section are from Infliximab for the treatment of adults with psoriasis (NICE technology appraisal guidance 134).

Infliximab, within its licensed indications, is recommended as a treatment option for adults with plaque psoriasis only when the following criteria are met:

- The disease is very severe as defined by a total PASI of 20 or more and a DLQI of more than 18.
- The psoriasis has failed to respond to standard systemic therapies such as ciclosporin, methotrexate or PUVA, or the person is intolerant to or has a contraindication to these treatments.

Infliximab treatment should be continued beyond 10 weeks only in people whose psoriasis has shown an adequate response to treatment within 10 weeks. An adequate response is defined as either:

- A 75% reduction in the PASI score from when treatment started (PASI 75) or
- A 50% reduction in the PASI score (PASI 50) and a 5-point reduction in the DLQI from when treatment started.

Ustekinumab

The recommendations in this section are from Ustekinumab for the treatment of adults with moderate to severe psoriasis (see the NGC summary of NICE technology appraisal guidance 180).

Ustekinumab is recommended as a treatment option for adults with plaque psoriasis when the following criteria are met:

- The disease is severe, as defined by a total PASI score of 10 or more and a DLQI score of more than 10.
- The psoriasis has not responded to standard systemic therapies, including ciclosporin, methotrexate and PUVA, or the person is intolerant of or has a contraindication to these treatments.
- The manufacturer provides the 90 mg dose (two 45 mg vials) for people who weigh more than 100 kg at the same total cost as for a single 45 mg vial.

Ustekinumab treatment should be stopped in people whose psoriasis has not responded adequately by 16 weeks after starting treatment. An adequate response is defined as either:

- A 75% reduction in the PASI score (PASI 75) from when treatment started or
- A 50% reduction in the PASI score (PASI 50) and a 5-point reduction in the DLQI score from when treatment started.

Changing to an Alternative Biological Drug

Consider changing to an alternative biological drug in adults if:

- The psoriasis does not respond adequately to a first biological drug as defined in NICE technology appraisals (at 10 weeks after starting treatment for infliximab, 12 weeks for etanercept, and 16 weeks for adalimumab and ustekinumab; primary failure) or
- The psoriasis initially responds adequately but subsequently loses this response, (secondary failure) or
- The first biological drug cannot be tolerated or becomes contraindicated

For adults in whom there is an inadequate response to a second biological drug, seek supra-specialist advice from a clinician with expertise in biological therapy.

Clinical Algorithm(s)

- There are several algorithms that accompany the original full guideline (see the Availability of Companion Documents field).
- In addition, the recommendations from this guideline have been incorporated into a NICE pathway.

Scope

Disease/Condition(s)

Psoriasis

Guideline Category

Evaluation

Management

Treatment

Clinical Specialty

Dermatology

Family Practice

Internal Medicine

Pediatrics

Pharmacology

Rheumatology

Intended Users

Advanced Practice Nurses

Nurses

Patients

Physician Assistants

Physicians

Guideline Objective(s)

To provide clear recommendations on the management of all types of psoriasis

Target Population

Children and adults with a diagnosis of psoriasis

Interventions and Practices Considered

Evaluation

1. Evaluation of disease severity and impact on people with psoriasis
    - Physician's and Patient's Global Assessment

    - Psoriasis Area and Severity Index (PASI)
    - Fitzpatrick Scale
    - Nail Psoriasis Severity Index
    - Dermatology Life Quality Index (DLQI) and Children's Dermatology Life Quality Index (CDLQI)
2. Assessment and referral for psoriatic arthritis
3. Identification of comorbidities

Management/Treatment

1. Topical therapy
    - Corticosteroids
    - Vitamin D analogues
    - Coal tar (with or without phototherapy)
    - Dithranol (with or without phototherapy)
2. Phototherapy (broad or narrow band ultraviolet B [UVB])
3. Photochemotherapy (psoralen and local ultraviolet [PUVA])
4. Systemic therapy
    - Ciclosporin
    - Methotrexate
    - Biological therapy
5. Self-management
6. Management of the psychological impact of psoriasis
7. Combination and sequencing of treatments
8. Patient education

Major Outcomes Considered

- Health related quality of life, (Children's Dermatology Life Quality Index [CDLQI]), Dermatology Life Quality Index [DLQI]), and/or European Quality of Life-5 Dimensions [EQ-5D])
- Scales of objective disease severity (Physician's Global Assessment, Psoriasis Area Severity Index [PASI])
- Length of hospital stay
- Time to recurrence
- Maintenance of remission/relapse rate
- Treatment adherence
- Withdrawal rates
- Adverse events
- Cost-effectiveness

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Searches of Unpublished Data

Description of Methods Used to Collect/Select the Evidence

Note from the National Guideline Clearinghouse (NGC): This guideline was developed by the National Clinical Guideline Centre (NCGC) on

behalf of the National Institute for Health and Clinical Excellence (NICE) (see the "Availability of Companion Documents" field for the full version of this guidance).

Developing the Review Questions and Outcomes

Review questions were developed in a PICO framework (patient, intervention, comparison and outcome) for intervention or experimental reviews, and with a framework of population, index tests, reference standard and target condition for reviews of diagnostic test accuracy, and population, presence or absence of risk factors and list of ideal minimum confounding factors for reviews of prognostic factors. This was to guide the literature searching process and to facilitate the development of recommendations by the guideline development group (GDG). A list of review questions is provided in section 4.1 of the full version of the guideline.

Searching for Evidence

Clinical Literature Search

Systematic literature searches were undertaken to identify evidence within published literature in order to answer the review questions as per The Guidelines Manual [2009]. Clinical databases were searched using relevant medical subject headings, free-text terms and study type filters where appropriate. Studies published in languages other than English were not reviewed. Where possible, searches were restricted to articles published in English language. All searches were conducted on core databases, MEDLINE, Embase, Cinahl and The Cochrane Library. Additional subject specific databases were used for some questions: e.g., PsycInfo for patient views. All searches were updated on 8th March 2012. No papers after this date were considered.

Search strategies were checked by looking at reference lists of relevant key papers, checking search strategies in other systematic reviews and asking the GDG for known studies. The questions, the study types applied, the databases searched and the years covered can be found in Appendix D of the full version of the original guideline document.

During the scoping stage, a topic-specific search was conducted for guidelines and reports on the websites listed below and on organisations relevant to the topic. Searching for grey literature or unpublished literature was not undertaken. All references sent by stakeholders were considered.

- Guidelines International Network database (www.g-i-n.net)
- National Guideline Clearinghouse (www.guideline.gov)
- National Institute for Health and Clinical Excellence (NICE) (www.nice.org.uk)
- National Institutes of Health Consensus Development Program (consensus.nih.gov/)
- National Library for Health (www.library.nhs.uk/)

Call for Evidence

The GDG decided to initiate a "call for evidence" for comparative data to address the question of whether biologics are safe and effective in people with chronic plaque psoriasis who have previously received another biological agent. The GDG believed that important evidence existed that would not be identified by the standard searches. The NCGC contacted all registered stakeholders and asked them to submit any relevant published or unpublished evidence. Evidence was received and noted in the relevant chapter of the full version of the original guideline document (Chapter 13).

Health Economic Literature Search

Systematic literature searches were also undertaken to identify health economic evidence within published literature relevant to the review questions. The evidence was identified by conducting a broad search relating to psoriasis in the National Health Service economic evaluation database (NHS EED), the Health Economic Evaluations Database (HEED) and health technology assessment (HTA) databases with no date restrictions. Additionally, the search was run on MEDLINE and Embase, with a specific economic filter, from 2008, to ensure recent publications that had not yet been indexed by these databases were identified. Studies published in languages other than English were not reviewed. Where possible, searches were restricted to articles published in English language.

The search strategies for health economics are included in Appendix D of the full guideline. All searches were updated on 8th March 2012. No papers published after this date were considered.

Evidence of Effectiveness

Inclusion/Exclusion

The GDG were consulted about any uncertainty regarding the inclusion/exclusion of selected studies. Note that this guideline did not consider the

management of psoriatic arthritis; therefore, studies that were primarily designed to investigate psoriatic arthritis rather than psoriasis affecting the skin were excluded. This was defined as studies primarily designed to treat the joint rather than the skin component of the disease and in a rheumatology rather than dermatology setting. However, studies were not excluded on the basis of the proportion of participants with psoriatic arthritis alone.

The GDG agreed that in most situations it would be reasonable to extrapolate data from adult populations to children when there was no or little data. Therefore, the GDG agreed to base treatment recommendations on randomised controlled trials (RCTs) with extrapolation to children if no separate paediatric evidence was found. Any exceptions to this principle will be noted in the LETR (linking evidence to recommendations) tables of the relevant review questions. Note that only two studies that specifically addressed psoriasis in children were identified and included in the guideline.

See section 4.3.1 and Appendix C in the full version of the original guideline document for details.

Type of Studies

For most intervention evidence reviews in this guideline, RCTs were included. Where the GDG believed RCT data would not be appropriate this is detailed in the protocols in Appendix C of the full guideline. RCTs were included as they are considered the most robust type of study design that could produce an unbiased estimate of the intervention effects.

For diagnostic evidence reviews, diagnostic cohorts and case controls studies were included and for prognostic reviews cohort studies were included.

Evidence of Cost-Effectiveness

Evidence on cost-effectiveness related to the key clinical issues being addressed in the guideline was sought. The health economist:

- Undertook a systematic review of the economic literature
- Undertook new cost-effectiveness analysis in priority areas

Inclusion/Exclusion for Cost-Effectiveness Studies

Full economic evaluations (studies comparing costs and health consequences of alternative courses of action: cost-utility, cost-effectiveness, cost-benefit and cost-consequence analyses) and comparative costing studies that addressed the review question in the relevant population were considered potentially applicable as economic evidence.

Studies that only reported cost per hospital (not per patient), or only reported average cost-effectiveness without disaggregated costs and effects, were excluded. Abstracts, posters, reviews, letters/editorials, foreign language publications and unpublished studies were excluded. Studies judged to have an applicability rating of "not applicable" were excluded (this included studies that took the perspective of a non-Organisation for Economic Co-operation and Development [OECD] country).

Remaining studies were prioritised for inclusion based on their relative applicability to the development of this guideline and the study limitations. For example, if a high-quality, directly applicable UK analysis was available other less relevant studies may not have been included. Where exclusions occurred on this basis, this is noted in the relevant section.

For more details about the assessment of applicability and methodological quality see the economic evaluation checklist (see the Guidelines Manual, Appendix H and the health economics research protocol in Appendix C of the full guideline).

When no relevant economic analysis was found from the economic literature review, relevant UK NHS unit costs related to the compared interventions were presented to the GDG to inform the possible economic implication of the recommendation to make.

Number of Source Documents

Refer to Appendix E of the full version of the original guideline for study selection flowcharts.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Overall Quality of Outcome Evidence in Grading of Recommendations Assessment, Development and Evaluation (GRADE)

Level	Description
High	Further research is very unlikely to change confidence in the estimate of effect
Moderate	Further research is likely to have an important impact on confidence in the estimate of effect and may change the estimate
Low	Further research is very likely to have an important impact on confidence in the estimate of effect and is likely to change the estimate
Very low	Any estimate of effect is very uncertain

Methods Used to Analyze the Evidence

Meta-Analysis

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Note from the National Guideline Clearinghouse (NGC): This guideline was developed by the National Clinical Guideline Centre (NCGC) on behalf of the National Institute for Health and Clinical Excellence (NICE) (see the "Availability of Companion Documents" field for the full version of this guidance).

Evidence of Effectiveness

The Research Fellow:

- Identified potentially relevant studies for each review question from the relevant search results by reviewing titles and abstracts – full papers were then obtained.
- Reviewed full papers against pre-specified inclusion/exclusion criteria to identify studies that addressed the review question in the appropriate population and reported on outcomes of interest (review protocols are included in Appendix C of the full guideline).
- Critically appraised relevant studies using the appropriate checklist as specified in The Guidelines Manual (see the "Availability of Companion Documents" field).
- Extracted key information about the study's methods and results into evidence tables (evidence tables are included in Appendix H of the full guideline).
- Generated summaries of the evidence by outcome (included in the relevant chapter write-ups):
    - Randomised studies: meta analysed, where appropriate and reported in Grading of Recommendations Assessment, Development and Evaluation (GRADE) profiles (for clinical studies)
    - Observational studies: data presented as a range of values in GRADE profiles
    - Diagnostic studies: data presented as a range of values in adapted GRADE profiles and a narrative summary is provided
    - Prognostic studies: data presented as a range of values in summary tables, with matrices for study quality

Methods of Combining Clinical Studies

Data Synthesis for Intervention Reviews

Where possible, meta-analyses were conducted to combine the results of studies for each review question using Cochrane Review Manager (RevMan5) software. Fixed-effects (Mantel-Haenszel) techniques were used to calculate risk ratios (relative risk) for the binary outcomes: clear/nearly clear or marked improvement, Psoriasis Area and Severity Index (PASI) 90, PASI 75, relapse, withdrawal due to toxicity, withdrawal due to lack of efficacy, skin atrophy, burn, cataracts, severe adverse events, concordance with treatment and service use. The continuous outcomes: change in PASI, change in Dermatology Life Quality Index (DLQI), duration of remission, number of ultraviolet (UV) treatments, time (or number of treatments) to remission, change in Hospital Anxiety and Depression Scale (HADS)/Beck Depression Inventory (BDI)/Speilberger State Trait Anxiety Inventory (STAI), change in Psoriasis Life Stress Inventory (PLSI), change in Psoriasis Disability Index

(PDI), change in HADS were analysed using an inverse variance method for pooling weighted mean differences and where the studies had different scales, standardised mean differences were used. Change scores were reported where available for continuous outcomes in preference to final values. However, if only final values were available, these were reported and meta-analysed with change scores. Where reported, time-to-event data were presented as a hazard ratio.

Statistical heterogeneity was assessed by considering the chi-squared test for significance at $p<0.1$ or an I-squared inconsistency statistic of >50% to indicate significant heterogeneity. Where significant heterogeneity was present, the guideline developers carried out sensitivity analysis based on the risk of bias of the studies if there were differences in study limitations, with particular attention paid to allocation concealment, blinding and loss to follow-up (missing data). In cases when significant heterogeneity was not explained by the above-mentioned sensitivity analyses, predefined subgroup analyses was carried out as specified in the review protocols.

Assessments of potential differences in effect between subgroups were based on the chi-squared tests for heterogeneity statistics between subgroups. If no sensitivity analysis was found to completely resolve statistical heterogeneity then a random effects (DerSimonian and Laird) model was employed to provide a more conservative estimate of the effect.

The means and standard deviations of continuous outcomes for each intervention group were required for meta-analysis. However, in cases where standard deviations were not reported, the standard error for the mean difference between groups was calculated if the p-values or 95% confidence intervals were reported and meta-analysis was undertaken with the mean difference and standard error using the generic inverse variance method in Cochrane Review Manager (RevMan5) software. Where p values were reported as "less than", a conservative approach was undertaken. For example, if p value was reported as "$p \leq 0.001$", the calculations for standard deviations would be based on a p value of 0.001. If these statistical measures were not available then the available data were reported in a narrative style but not included in the meta-analysis.

For binary outcomes, absolute event rates were also calculated using the GRADEpro software using event rate in the control arm of the pooled results.

Network meta-analysis was conducted for the review questions on the topical therapies for chronic plaque psoriasis at the trunk and limbs and high impact/difficult-to-treat sites. This allowed indirect comparisons of all the drugs included in the review when no direct comparison was available.

See section 4.3.2 of the full guideline document for additional information on data synthesis for intervention reviews.

Data Synthesis for Prognostic Factor Reviews

Odds ratios, relative risks or hazard ratios, with their 95% confidence intervals, from multivariate analyses were extracted from the papers. Data were not combined in a meta-analysis for observational studies. Sensitivity analyses were carried out on the basis of study quality and results were reported as ranges.

Data Synthesis for Diagnostic Test Accuracy Reviews

For diagnostic test accuracy studies, the following outcomes were reported: sensitivity, specificity, positive predictive value, negative predictive value, likelihood ratio and pre- and post-test probabilities. In cases where the outcomes were not reported, 2 by 2 tables were constructed from raw data to allow calculation of these accuracy measures. Where possible the results for sensitivity and specificity were presented using Cochrane Review Manager (RevMan5) software.

Data Synthesis for Diagnostic Test Validity and Reliability Review

For investigating test validity and reliability of scales recording the severity and impact of psoriasis, the following outcomes were reported: Convergent validity, discriminate validity, internal consistency, inter-rater reliability, intra-rater reliability, practicability and sensitivity to change. Appropriate statistics were reported for each of these outcomes with their 95% confidence intervals or standard deviations for mean values where possible: Pearson product-moment correlation coefficient, Spearman rank correlation coefficient, kappa statistics, intra-class correlation, internal consistency coefficients (Crohnbach's alpha) and time to administer the test. Data were summarised across outcomes and comparisons in a tabular format and any heterogeneity was assessed.

Types of Analysis

Estimates of effect from individual studies were based on a modified available case analysis (ACA) where possible or on an intention to treat (ITT) analysis if this was not possible.

ACA analysis is where only data that was available for participants at the follow-up point is analysed, without making any imputations for missing data. In the modification for binary outcomes, participants known to have dropped out due to lack of efficacy were included in the denominator for

efficacy outcomes and those known to have dropped out due to adverse events were included in the numerator and denominator when analysing adverse events. This method was used rather than intention-to-treat analysis to avoid making assumptions about the participants for whom outcome data were not available, and rather assuming that those who drop out have the same event rate as those who continue. This also avoids incorrectly weighting studies in meta-analysis and overestimating the precision of the effect by using a denominator that does not reflect the true sample size with outcome data available. If there was a high drop-out rate for a study then a sensitivity analysis was performed to determine whether the effect was changed by using an intention-to-treat analysis. If this was the case both analyses would be presented.

ITT analysis is where all participants that were randomised are considered in the final analysis based on the intervention and control groups to which they were originally assigned. It was assumed that participants in the trials lost to follow-up did not experience the outcome of interest (categorical outcomes) and they would not considerably change the average scores of their assigned groups (for continuous outcomes). It is important to note that ITT analyses tend to bias the results towards no difference. ITT analysis is a conservative approach to analyse the data, and therefore the effect may be smaller than in reality.

Unit of Analysis

This guideline includes RCTs with different units of analysis. Some studies randomised individual participants to the intervention (parallel or between-patient studies) while others randomised body halves to the intervention (within-patient studies, analogous to crossover trials).

It was recognised that data from within-patient trials should be adjusted for the correlation coefficient relating to the comparison of paired data. Therefore, if sufficient data were available, this was calculated and the standard error was adjusted accordingly.

Additionally, within- and between-patient data were pooled, accepting that this may result in underweighting of the within-patient studies; however, it is noted that this is a conservative estimate. Sensitivity analyses were undertaken to investigate whether the effect size varied consistently for within- and between-patient studies and there was no evidence that the size of effect varied in a systematic way.

Appraising the Quality of Evidence by Outcomes

The evidence for outcomes from the included randomised controlled trials (RCTs) and observational intervention studies were evaluated and presented using an adaptation of the "Grading of Recommendations Assessment, Development and Evaluation (GRADE) toolbox" developed by the international GRADE working group (http://www.gradeworkinggroup.org /). The software (GRADEpro) developed by the GRADE working group was used to assess the quality of each outcome, taking into account individual study quality and the meta-analysis results. The summary of findings was presented as one table in the guideline (called clinical evidence profiles). This includes the details of the quality assessment pooled outcome data, and where appropriate, an absolute measure of intervention effect and the summary of quality of evidence for that outcome. In this table, the columns for intervention and control indicate the sum of the study arm sample sizes for continuous outcomes. For binary outcomes such as number of patients with an adverse event, the event rates (n/N across studies: sum of the number of patients with events divided by sum of number of patients) are shown with percentages. This is for information only and is not intended to show pooling (which was performed using a weighted meta-analysis as described above). Reporting or publication bias was only taken into consideration in the quality assessment and included in the Clinical Study Characteristics table if it was apparent.

Each outcome was examined separately for the quality elements listed and defined in Table 1 of the full guideline document, and each graded using the quality levels listed in Table 2 of the full guideline document. The main criteria considered in the rating of these elements are discussed below. Footnotes were used to describe reasons for grading a quality element as having serious or very serious problems. The ratings for each component were summed to obtain an overall assessment for each outcome (see the "Rating Scheme for the Strength of the Evidence" field).

Grading the Quality of Clinical Evidence

After results were pooled, the overall quality of evidence for each outcome was considered. The following procedure was adopted when using GRADE:

1. A quality rating was assigned, based on the study design. RCTs start HIGH and observational studies as LOW.
2. The rating was then downgraded for the specified criteria: Study limitations, inconsistency, indirectness, imprecision and reporting bias. These criteria are detailed in the full version of the original guideline. Observational studies were upgraded if there was: a large magnitude of effect, dose-response gradient, and if all plausible confounding would reduce a demonstrated effect or suggest a spurious effect when results showed no effect. Each quality element considered to have "serious" or "very serious" risk of bias was rated down -1 or -2 points respectively.
3. The downgraded/upgraded marks were then summed and the overall quality rating was revised. For example, all RCTs started as HIGH and the overall quality became MODERATE, LOW or VERY LOW if 1, 2 or 3 points were deducted respectively.
4. The reasons or criteria used for downgrading were specified in the footnotes.

Additional information related to factors that affect quality such as study limitations, inconsistency, indirectness, and imprecision are detailed in the full guideline document.

Evidence of Cost-Effectiveness

Literature Review

The Health Economist:

- Identified potentially relevant studies for each review question from the economic search results by reviewing titles and abstracts – full papers were then obtained.
- Reviewed full papers against pre-specified inclusion/exclusion criteria to identify relevant studies
- Critically appraised relevant studies using the economic evaluations checklist as specified in The Guidelines Manual.
- Extracted key information about the study's methods and results into evidence tables (evidence tables are included in Appendix I of the full guideline document).
- Generated summaries of the evidence in NICE economic evidence profiles (included in the relevant chapter write-ups in the full guideline document).

NICE Economic Evidence Profiles

The NICE economic evidence profile has been used to summarise cost and cost-effectiveness estimates. The economic evidence profile shows, for each economic study, an assessment of applicability and methodological quality, with footnotes indicating the reasons for the assessment. These assessments were made by the health economist using the economic evaluation checklist from The Guidelines Manual, Appendix H. It also shows incremental costs, incremental outcomes (for example, quality-adjusted life-years [QALYs]) and the incremental cost-effectiveness ratio from the primary analysis, as well as information about the assessment of uncertainty in the analysis. If a non-UK study was included in the profile, the results were converted into pounds sterling using the appropriate purchasing power parity.

Where economic studies compare multiple strategies, results are reported at the end of the relevant chapter in an alternative table summarising the study as a whole A comparison is "appropriate" where an intervention is compared with the next most expensive non-dominated option – a clinical strategy is said to "dominate" the alternatives when it is both more effective and less costly. Footnotes indicate if a comparison was "inappropriate" in the analysis.

Undertaking New Health Economic Analysis

As well as reviewing the published economic literature for each review question, as described above, new economic analysis was undertaken by the Health Economist in priority areas. Priority areas for new health economic analysis were agreed by the GDG after formation of the review questions and consideration of the available health economic evidence.

Additional data for the analysis was identified as required through additional literature searches undertaken by the Health Economist, and discussion with the GDG. Model structure, inputs and assumptions were explained to and agreed by the GDG members during meetings, and they commented on subsequent revisions.

See Appendices M, N and O of the full guideline document for details of the health economic analyses undertaken for the guideline.

Cost-Effectiveness Criteria

NICE's report "Social value judgements: principles for the development of NICE guidance" sets out the principles that GDGs should consider when judging whether an intervention offers good value for money.

In general, an intervention was considered to be cost effective if either of the following criteria applied (given that the estimate was considered plausible):

- The intervention dominated other relevant strategies (that is, it was both less costly in terms of resource use and more clinically effective compared with all the other relevant alternative strategies), or
- The intervention cost less than £20,000 per QALY gained compared with the next best strategy

If the GDG recommended an intervention that was estimated to cost more than £20,000 per QALY gained, or did not recommend one that was estimated to cost less than £20,000 per QALY gained, the reasons for this decision are discussed explicitly in the "From evidence to recommendations" section of the relevant chapter of the full guideline document with reference to issues regarding the plausibility of the estimate or to the factors set out in the "Social value judgements: principles for the development of NICE guidance."

When QALYs or life years gained are not used in the analysis, results are difficult to interpret unless one strategy dominates the others with respect to every relevant health outcome and cost.

Methods Used to Formulate the Recommendations

Expert Consensus

Informal Consensus

Description of Methods Used to Formulate the Recommendations

Note from the National Guideline Clearinghouse (NGC): This guideline was developed by the National Clinical Guideline Centre (NCGC) on behalf of the National Institute for Health and Clinical Excellence (NICE) (see the "Availability of Companion Documents" field for the full version of this guidance).

A multidisciplinary Guideline Development Group (GDG) comprising professional group members and consumer representatives of the main stakeholders developed this guideline. The group met every four weeks during the development of the guideline.

Staff from the NCGC provided methodological support and guidance for the development process. The team working on the guideline included a project manager, research fellows, health economists and information scientists. They undertook systematic searches of the literature, appraised the evidence, conducted meta-analysis and cost-effectiveness analysis where appropriate and drafted the guideline in collaboration with the GDG.

Developing Recommendations

Over the course of the guideline development process, the GDG was presented with:

- Evidence tables of the clinical and economic evidence reviewed from the literature. All evidence tables are in Appendix H and Appendix I of the full guideline document.
- Summary of clinical and economic evidence and quality (as presented in chapters 6-14 of the full guideline document).
- Forest plots (see Appendix J of the full guideline document).
- A description of the methods and results of the cost-effectiveness analysis undertaken for the guideline (see Appendix M, Appendix N and Appendix O of the full guideline document).

Recommendations were drafted on the basis of the GDG interpretation of the available evidence, taking into account the balance of benefits, harms and costs. When clinical and economic evidence was of poor quality, conflicting or absent, the GDG drafted recommendations based on their expert opinion. The considerations for making consensus based recommendations include the balance between potential harms and benefits, economic or implications compared to the benefits, current practices, recommendations made in other relevant guidelines, patient preferences and equality issues. The consensus recommendations were reached through discussions by the GDG. The GDG may also consider whether the uncertainty is sufficient to justify delaying making a recommendation to await further research, taking into account the potential harm of failing to make a clear recommendation.

The main considerations specific to each recommendation are outlined in the "Linking Evidence to Recommendation" section preceding the recommendation section in the full guideline document.

Rating Scheme for the Strength of the Recommendations

Not applicable

Cost Analysis

Relevant health economic evidence for recommendations can be found in the specific chapters of the full version of the original guideline document.

Additional information regarding health economics is provided in Appendices M, N, O, and P of the full guideline document.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

The guideline was validated through two consultations.

1. The first draft of the guideline (the full guideline, National Institute for Health and Clinical Excellence [NICE] guideline, and Quick Reference Guide) were consulted with Stakeholders and comments were considered by the Guideline Development Group (GDG)
2. The final consultation draft of the Full guideline, the NICE guideline and the Information for the Public were submitted to stakeholders for final comments.

The final draft was submitted to the Guideline Review Panel for review prior to publication.

Evidence Supporting the Recommendations

References Supporting the Recommendations

Feldman SR, Krueger GG. Psoriasis assessment tools in clinical trials. Ann Rheum Dis. 2005 Mar;64(Suppl 2):ii65-8. [24 references] PubMed

Ibrahim GH, Buch MH, Lawson C, Waxman R, Helliwell PS. Evaluation of an existing screening tool for psoriatic arthritis in people with psoriasis and the development of a new instrument: the Psoriasis Epidemiology Screening Tool (PEST) questionnaire. Clin Exp Rheumatol. 2009 May-Jun;27(3):469-74. PubMed

Rich P, Scher RK. Nail Psoriasis Severity Index: a useful tool for evaluation of nail psoriasis. J Am Acad Dermatol. 2003 Aug;49(2):206-12. PubMed

Type of Evidence Supporting the Recommendations

The type of evidence supporting the recommendations is not specifically stated.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Delivery of high-quality healthcare and improved outcomes for people with psoriasis

Potential Harms

Corticosteroids

Continuous use of potent or very potent corticosteroids may cause:

- Irreversible skin atrophy and striae
- Psoriasis to become unstable

- Systemic side effects when applied continuously to extensive psoriasis (for example, more than 10% of body surface area affected)

Methotrexate

Methotrexate can cause a clinically significant rise in transaminases and long-term therapy may be associated with liver fibrosis.

Psoralen with Local Ultraviolet A (PUVA)

Exposure to PUVA is associated with an increased risk of skin cancer (squamous cell carcinoma), and this risk is related to the number of PUVA treatments. Subsequent use of ciclosporin may increase the risk of skin cancer, particularly if patients have already received more than 150 PUVA treatments.

Use PUVA with caution or consider other treatment options in:

- People at risk of skin cancer (melanoma and non-melanoma type)
- People with lighter skin types, such as skin types I or II on the Fitzpatrick scale
- People who are likely to require ciclosporin or long-term methotrexate
- Young people

See also appendix B of the original guideline document for details of the risk-benefit profiles of interventions recommended in this guideline.

Contraindications

Contraindications

- Do not use psoralen with local ultraviolet A (PUVA) in people with psoriasis of any type and a genetic predisposition to skin cancer for example, xeroderma pigmentosum or familial melanoma.
- Do not use PUVA when other appropriate treatments are available in:
    - People with a personal history of skin cancer or
    - People who have already received 150 PUVA treatments
    - Children

Qualifying Statements

Qualifying Statements

- This guidance represents the view of the National Institute for Health and Clinical Excellence (NICE), which was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer, and informed by the summary of product characteristics of any drugs they are considering.
- Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties.
- The guideline will assume that prescribers will use a drug's summary of product characteristics to inform decisions made with individual patients.
- This guideline recommends some drugs for indications for which they do not have a UK marketing authorisation at the date of publication, if there is good evidence to support that use. The prescriber should follow relevant professional guidance, taking full responsibility for the decision.
- Treatment and care should take into account patients' needs and preferences. People with psoriasis should have the opportunity to make informed decisions about their care and treatment, in partnership with their healthcare professionals. If patients do not have the capacity to make decisions, healthcare professionals should follow the Department of Health's advice on consent and the code of practice that

accompanies the Mental Capacity Act. In Wales, healthcare professionals should follow advice on consent from the Welsh Government.

Implementation of the Guideline

Description of Implementation Strategy

The National Institute for Health and Clinical Excellence (NICE) has developed tools to help organisations implement this guidance. These are available on the NICE Web site (http://guidance.nice.org.uk/cg153 ; see also the "Availability of Companion Documents" field).

Key Priorities for Implementation

The following recommendations have been identified as priorities for implementation.

Assessment Tools for Disease Severity and Impact and When to Refer for Specialist Care

For people with any type of psoriasis assess:

- Disease severity
- The impact of disease on physical, psychological and social wellbeing
- Whether they have psoriatic arthritis
- The presence of comorbidities

Following assessment in a non-specialist setting, refer people for dermatology specialist advice if:

- There is diagnostic uncertainty or
- Any type of psoriasis is severe or extensive, for example more than 10% of the body surface area is affected or
- Any type of psoriasis cannot be controlled with topical therapy or
- Acute guttate psoriasis requires phototherapy or
- Nail disease has a major functional or cosmetic impact or
- Any type of psoriasis is having a major impact on a person's physical, psychological or social wellbeing

Assessment and Referral for Psoriatic Arthritis

- As soon as psoriatic arthritis is suspected, refer the person to a rheumatologist for assessment and advice about planning their care.

Identification of Comorbidities

Discuss risk factors for cardiovascular comorbidities with people who have any type of psoriasis (and their families or carers where appropriate). Where appropriate offer preventative advice, healthy lifestyle information and support for behavioural change tailored to meet the needs of the individual in line with the following NICE guidance:

- Lipid modification (NICE clinical guideline 67)
- Obesity (NICE clinical guideline 43)
- Preventing type 2 diabetes: population and community interventions (NICE public health guidance 35)
- Prevention of cardiovascular disease (NICE public health guidance 25)
- Alcohol-use disorders: preventing harmful drinking (NICE public health guidance 24)
- Smoking cessation services (NICE public health guidance 10)
- Four commonly used methods to increase physical activity (NICE public health guidance 2)
- Promoting physical activity in the workplace (NICE public health guidance 13)
- Promoting physical activity for children and young people (NICE public health guidance 17)

Topical Therapy: General Recommendations

Offer practical support and advice about the use and application of topical treatments. Advice should be provided by healthcare professionals who are trained and competent in the use of topical therapies. Support people to adhere to treatment in line with Medicines adherence

(NICE clinical guideline 76).

Topical Therapy: Topical Treatment of Psoriasis Affecting the Trunk and Limbs

Offer a potent corticosteroid applied once daily plus vitamin D or a vitamin D analogue applied once daily (applied separately, one in the morning and the other in the evening) for up to 4 weeks as initial treatment for adults with trunk or limb psoriasis.

Phototherapy (Broad- or Narrow-Band Ultraviolet B Light)

Offer narrowband ultraviolet B (UVB) phototherapy to people with plaque or guttate-pattern psoriasis that cannot be controlled with topical treatments alone. Treatment with narrowband UVB phototherapy can be given 3 or 2 times a week depending on patient preference. Tell people receiving narrowband UVB that a response may be achieved more quickly with treatment 3 times a week.

Systemic Non-biological Therapy

Offer systemic non-biological therapy to people with any type of psoriasis if:

- It cannot be controlled with topical therapy and
- it has a significant impact on physical, psychological or social wellbeing and
- One or more of the following apply:
    - Psoriasis is extensive (for example, more than 10% of body surface area affected or a Psoriasis Area and Severity Index (PASI) score of more than 10) or
    - Psoriasis is localised and associated with significant functional impairment and/or high levels of distress (for example severe nail disease or involvement at high-impact sites) or
    - Phototherapy has been ineffective, cannot be used or has resulted in rapid relapse (rapid relapse is defined as greater than 50% of baseline disease severity within 3 months)

Choice of Drugs (Systemic non-biological Therapy)

Offer methotrexate as the first choice of systemic agent for people with psoriasis who fulfil the criteria for systemic therapy except in the circumstances described in recommendations 1.5.2.4 and 1.5.2.12 of the original guideline document.

Changing to an Alternative Biological Drug (Systemic Biological Therapy)

Consider changing to an alternative biological drug in adults if:

- The psoriasis does not respond adequately to a first biological drug as defined in NICE technology appraisals (at 10 weeks after starting treatment for infliximab, 12 weeks for etanercept, and 16 weeks for adalimumab and ustekinumab; primary failure) or
- The psoriasis initially responds adequately but subsequently loses this response, (secondary failure) or
- The first biological drug cannot be tolerated or becomes contraindicated

Implementation Tools

Audit Criteria/Indicators

Clinical Algorithm

Patient Resources

Resources

Tool Kits

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

National Clinical Guideline Centre. Psoriasis: the assessment and management of psoriasis. London (UK): National Institute for Health and Clinical Excellence (NICE); 2012 Oct. 61 p. (Clinical guideline; no. 153).

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2012 Oct

Guideline Developer(s)

National Guideline Centre - National Government Agency [Non-U.S.]

Source(s) of Funding

National Institute for Health and Clinical Excellence (NICE)

Guideline Committee

Guideline Development Group (GDG)

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Financial Disclosures/Conflicts of Interest

At the start of the guideline development process all Guideline Development Group (GDG) members declared interests including consultancies, fee-paid work, share-holdings, fellowships and support from the healthcare industry. At all subsequent GDG meetings, members declared arising conflicts of interest, which were also recorded. Members were either required to withdraw completely or for part of the discussion if their declared interest made it appropriate.

The details of declared interests and the actions taken are shown in Appendix B of the full version of the original guideline document (see the "Availability of Companion Documents" field).

Guideline Status

This is the current release of the guideline.

Guideline Availability

Electronic copies: Available from the National Institute for Health and Clinical Excellence (NICE) Web site .

Availability of Companion Documents

The following are available:

- Psoriasis: the assessment and management of psoriasis. Full guideline. London (UK): National Institute for Health and Clinical Excellence (NICE); 2012 Oct. 760 p. (Clinical guideline; no. 153). Electronic copies: Available in Portable Document Format (PDF) from the National Institute for Health and Clinical Excellence (NICE) Web site .
- Psoriasis: the assessment and management of psoriasis. Appendices. London (UK): National Institute for Health and Clinical Excellence (NICE); 2012 Oct. (Clinical guideline; no. 153). Electronic copies: Available in PDF from the NICE Web site .
- Psoriasis. Algorithm. London (UK): National Institute for Health and Clinical Excellence (NICE); 2012 Oct. 7p. (Clinical guideline; no. 153). Electronic copies: Available in PDF from the NICE Web site .
- Psoriasis: the assessment and management of psoriasis. Baseline assessment tool. London (UK): National Institute for Health and Clinical Excellence (NICE); 2012 Oct. (Clinical guideline; no. 153). Electronic copies: Available from the NICE Web site .
- Psoriasis: the assessment and management of psoriasis. Clinical audit tools. London (UK): National Institute for Health and Clinical Excellence (NICE); 2012 Oct. (Clinical guideline; no. 153). Electronic copies: Available from the NICE Web site .
- Psoriasis: the assessment and management of psoriasis. Costing report. London (UK): National Institute for Health and Clinical Excellence (NICE); 2012 Oct. 20 p.(Clinical guideline; no. 153). Electronic copies: Available in PDF from the NICE Web site .
- Psoriasis: the assessment and management of psoriasis. Costing template. London (UK): National Institute for Health and Clinical Excellence (NICE); 2012 Oct. (Clinical guideline; no. 153). Electronic copies: Available from the NICE Web site .
- Psoriasis overview. NICE pathway. London (UK): National Institute for Health and Clinical Excellence (NICE); 2012 Oct. (Clinical guideline; no. 153). Electronic copies: Available from the NICE Web site .
- The guidelines manual 2009. London (UK): National Institute for Health and Clinical Excellence (NICE); 2009 Jan. Electronic copies: Available in Portable Document Format (PDF) from the NICE Archive Web site .

Patient Resources

The following is available:

- Psoriasis. Information for the public. London: National Institute for Health and Clinical Excellence (NICE); 2012 Oct. Electronic copies: Available from the National Institute for Health and Clinical Excellence (NICE) Web site .

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

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